

Docket No. 3086-A

Appl. No. 09/981,421  
Resp to OA dated Dec. 3, 2004  
Resp. filed June 2, 2005

### REMARKS

In view of the following remarks, Applicants respectfully request reconsideration of the claims pending in this application. Claims 1-3 and 6-15 are pending and claims 1, 6, 7 and 9-15 are under consideration. No claims are allowed. In the discussion that follows Applicants address each of the objections and rejections in the order that they appear in the Office Action mailed December 3, 2004.

Claim 1 and dependent claims 6, 7 and 9-15 are rejected under 35 U.S.C. 112, first paragraph, because the Examiner is of the opinion that the specification does not reasonably provide enablement for claims to a method of treating renal failure due to ischemia using IL-18R antibody. The Examiner refers to the Wands factors as to be considered for determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue". A specification is enabling if it teaches one skilled in the art to make and use the claimed invention without undue experimentation. That some experimentation may be required is not fatal; (In re Vaack, 20 USPQ2d 1438 (Fed Cir. 1991)). Applicants submit that the specification provides sufficient teaching to enable one skilled in the art to treat renal failure due to ischemia. For example, beginning at page 10 line 20 and continuing until at least page 13 line 14, the specification teaches routes of administration, dosing considerations, course of dosing etc. Furthermore, it is well settled that it is routine for one skilled in the art to optimize therapeutic dosing parameters. Accordingly, such routine optimization is not undue experimentation.

The Examiner appears to be of the opinion that the specification must establish a connection with renal failure and antagonizing IL-18. However, the law does not require this. Nevertheless, Applicants herewith provide the following journal article and abstract that support Applicants' teaching of treating renal failure with IL-18R antibodies.

1. Melnikov, V. et al., *J. Clin. Invest.*, 107(9):1145-1152, May 2001;
2. Parikh, C.R. et al., *Am. J. of Kidney Dis.*, 43(3):405-414, Mar. 2004.

In view of the above comments, Applicants submit that the present specification enables treating renal failure with IL-18R Ab and respectfully requests that the Examiner withdraw this rejection.

The Examiner also rejects claims 1, 6, 9-12, 14 and 15 under 35 U.S.C. 103(a) as being unpatentable over Ahdel-Meguid in view of Torigoe et al. The Ahdel-Meguid reference is a US patent that was the result of an International Application filed March 17, 2000. Thus, this patent is effective as prior art in accordance with Section 102(e) that was in effect on November 28, 2000. The 102(e) date is August 31, 2001. Thus, the primary reference is not prior art to the present application, having a priority date of October 18, 2000.

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Since the Ahdel-Meguid reference is not prior art and improperly cited, this rejection is overcome and Applicants request that the rejection be withdrawn.

The Examiner further rejects claim 7 under 35 U.S.C. 103(a) as being unpatentable over Ahdel-Meguid et al. in view of Torigoe et al. as applied to claims 1, 6, 9-12, 14 and 15 in the previous discussion and further in view of Huston et al. The Ahdel-Meguid reference is a US patent that was the result of an International Application filed March 17, 2000. Thus, this patent is effective as prior art in accordance with Section 102(e) that was in effect on November 28, 2000. The 102(e) date is August 31, 2001. Thus, the primary reference is not prior art to the present application having a priority date of October 18, 2000. Since the Ahdel-Meguid reference is not prior art and improperly cited, this rejection is overcome and Applicants request that the rejection be withdrawn.

The Examiner also rejects claim 13 under 35 U.S.C. 103(a) as being unpatentable over Ahdel-Meguid et al. in view of Torigoe et al. and further in view of Jacobs et al. Applicants repeat the comments made above: The Ahdel-Meguid reference is a US patent that was the result of an International Application filed March 17, 2000. Thus, this patent is effective as prior art in accordance with Section 102(e) that was in effect on November 28, 2000. The 102(e) date is August 31, 2001. Thus, the primary reference is not prior art to the present application having a priority date of October 18, 2000. Since the Ahdel-Meguid reference is not prior art and improperly cited, this rejection is overcome and Applicants request that the rejection be withdrawn.

In view of the foregoing remarks Applicants submit that the claims are now in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,



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Signed:   
Nanci M. Kertson

Date: June 2, 2005